K081341
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SECTION 5: 510(k) SUMMARY
[as required by section 807.92(c)]

A. Submitter's Information:

Name:	Thomas Medical Products, Inc.
Address:	65 Great Valley Parkway Malvern, PA 19355
Telephone Number:	610.296.3000
Facsimile:	610.296.4591
Contact Person:	Tim Stoudt
Title:	Manager, QA / RA
Date Submission Prepared:	November 8, 2007

MAY 14 2008

B. Device Information:

Trade name:	Not assigned at the time of submission
Classification Name(s):	Catheter Introducer (21 CFR §870.1340)
Common or usual name(s):	Reinforced Catheter Introducer System (RCIS)

C. Legally marketed device to which equivalence is claimed:

Arrow Transseptal Super Arrow-Flex Percutaneous Sheath (K970229)
Terumo Medical Corporation Pinnacle Destination Peripheral Guiding Sheath (K051601)

D. Description of the device:

The RCIS consists of a spiral reinforced sheath introducer and an appropriately sized dilator packaged in a tyvek/polymylar pouch.

Each reinforced introducer sheath features an integrated hemostasis valve system with a sideport extension and a 3-way stopcock. Each introducer also has a radiopaque distal tip to aid the physician is correct placement of the device.

The RCIS dilator is lockable to the mating reinforced introducer sheath. The dilator has a straight curve configuration that extends approximately 2.5cm beyond the matching sheath when the dilator is locked to the sheath. The dilator is compatible with an up to 0.038" diameter guidewire.

E. Intended use of the device:

The RCIS is indicated for use in arterial and venous procedures requiring percutaneous introduction of therapeutic or diagnostic intravascular devices.

F. Summary of the technological characteristics of the device compared to the predicate devices:

Features	TMP Reinforced Sheath [XD-2809-00]	Super Arrow Flex [CL-07690]	Terumo Pinnacle Destination [RSC05]
Hemostasis valve provided	Yes	Yes	Yes
Compatible with .038" guide wire	Yes	Yes	Yes
Introducer available in 90cm length	Yes	Yes	Yes
Introducer set available in 6F	Yes	Yes	Yes
Introducer reinforced with a flat metal wire	Yes	Yes	Yes
Wire reinforcement completely encapsulated	Yes	Yes	Yes
Radiopaque tip or marker	Yes	Yes	Yes
Sideport extension with 3-way stopcock	Yes	Yes	Yes
At least one matching dilator	Yes	Yes	Yes

G. Substantial equivalence rationale:

Thomas Medical Products, Inc. considers the Reinforced Catheter Introducer System substantially equivalent to the currently marketed predicate devices. This assessment is based upon analysis of similar technological characteristics, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2008

Intertek Testing Services
c/o Mr. Jay Y. Kogoma
2307 E. Aurora Road, Unit 87
Twinsburg, OH 44087

Re: K081341
Reinforced Catheter Introducer System
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer Catheter
Regulatory Class: Class II (two)
Product Code: DYB
Dated: May 12, 2008
Received: May 13, 2008

Dear Mr. Kogoma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K081341

Device Name: Reinforced Catheter Introducer System

Indications For Use:

The [Reinforced Catheter Introducer System]* is indicated for use in arterial and venous procedures requiring percutaneous introduction of therapeutic or diagnostic intravascular devices.

*[or tradename]

Prescription Use X (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter-Use _____ (Per 21 CFR 801 Subpart C)

(Optional Format 11-13-03)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K081341

510(k) "Indications For Use" Form (Replica of FDA Form)